K000778

MAY - 3 2000

510(k) Summary of Safety and Effectiveness
ArthroCare, Corporation
ENTec® ReFlex™ Wand

General Information

Manufacturer:
ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94086-2916

Establishment Registration Number: 2951580

Contact Person:
Bruce Prothro
Vice President, Regulatory Affairs and
Quality Assurance

Date Prepared: April 14, 2000

Device Description

Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Trade Name: ENTec® ReFlex™ Wand

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

ENTec ReFlex Wand	K000036
ENTec Surgery System	K973478
Somnus Somnoplasty™ System	K973618
Ellman Surgitron IEC	K990146

Intended Use

The ENTec ReFlex Wand is intended to be used with the ENTec Surgery System for ablation and coagulation of soft tissue in otolaryngological (ENT) procedures, including the treatment of snoring, nasal airway obstruction by reduction of hypertrophic nasal turbinates, and submucosal tissue shrinkage.

Product Description

The ENTec ReFlex Wand is a bipolar electrosurgery probe, which is used in conjunction with the ENTec Surgery System.

Substantial Equivalence

In establishing substantial equivalence to the predicate devices, ArthroCare compared the indications for use, materials, product specifications and energy requirements of the electrosurgical probes as well as for the entire systems. Additionally, performance testing has been completed to demonstrate the substantial equivalence of the ENTec ReFlex Wand to the predicate devices. The performance testing and device comparison demonstrated that the subject device is substantially equivalent to the predicate devices, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2000

Mr. Bruce Prothro
Vice President, Regulatory Affairs and Quality Assurance
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94086-2916

Re: K000778
Trade Name: ENTec™ Reflex™ Wand
Regulatory Class: II
Product Code: GEI
Dated: March 8, 2000
Received: March 10, 2000

Dear Mr. Prothro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: ENTec® ReFlex™ Wand
510(k) Number: K000778

Indications for use:

The ENTec ReFlex Wand is intended to be used with the ENTec Surgery System for ablation and coagulation of soft tissue in otolaryngological (ENT) procedures, including the treatment of snoring, nasal airway obstruction by reduction of hypertrophic nasal turbinates, and submucosal tissue shrinkage.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Vochmer.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000778

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-the-Counter Use